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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,559	12/07/2000	Tetsuyoshi Ishiwata	766.21 CIP	9523

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/25/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.

09/730,559

Applicant(s)

Ishiwata, T. et al.

Examiner

Joseph Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 4, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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Election/Restriction

This application, filed December 7, 2000, is a continuation in part of application 09/090,672, filed June 4, 1998, which is a continuation in part of PCT/JP97/04468, filed December 5, 1997.

The reply filed on December 4, 2002, paper number 16, is not fully responsive to the prior Office Action because Applicants failed to elect a single group for examination. Applicants indicated that six groups were subject to restriction requirement, however the restriction requirement indicates that there are 128 groups where each number represents a single group and a single invention. Further, the election of a specific sequence for examination is not a species election. For example, as indicated in Applicants election '1-37' is not a single invention, rather it is 37 separate and different inventions each directed to one of the SEQ ID NOs: 1-33, 41- 44 listed in the claims. If Applicants elect for examination 'a DNA related to IgA nephropathy', Applicants must choose one invention directed to one SEQ ID NO for examination. For example, if Applicants elect for examination the DNA as set forth in SEQ ID NO: 7 as the DNA related to IgA nephropathy, invention number seven must be elected.

Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer,

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within which to supply the omission or correction in order to avoid abandonment.

EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

The restriction requirement is reiterated below for Applicants' convenience.

Claims 1-21 are pending and currently under examination.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 1-37. Claims 1-3, 5, 7, 10-13, 18 and 19, drawn to a DNA related to IgA nephropathy as set forth in SEQ ID NOs: 1-33, 41-44 (37 separate and different sequences set forth in the claim), classified in class 536, subclass 23.1.
- 38-75. Claim 4, drawn to a method for detecting IgA nephropathy-related genes using the sequences set forth in claim 1 and those derived from those sequences as set forth in claim 3 (37 separate and different complete sequences), classified in class 435, subclass 6.
- 76-113. Claim 6, drawn to a method of inhibiting transcription of IgA nephropathy-related genes (each of the separate sequences set forth in claim 1 represent a unique method), classified in class 514, subclass 44.
114. Claim 8, drawn to a method of isolating a gene related to IgA nephropathy by differential display, classified in class 435, subclass 91.5.

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- 115-121. Claim 9, drawn to a protein as set forth in SEQ ID NOS: 34-40 (seven separate proteins), classified in class 530, subclass 350.
- 122-128. Claims 14-17, 20 and 21, drawn to an antibody which recognizes the protein as set forth in claim 9 (seven separate proteins), classified in class 424, subclass 130.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-37, 115-121 and 122-128 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise polynucleotides, proteins and antibodies, each having a different physical and chemical structures. Further, it is noted that each of the specific sequences set forth in each of the inventions are unique one to the other, and would not anticipate or make obvious each other. Each of the different sequences would require a separate search. The differences between the inventions are further underscored by their divergent classification.

Inventions 38-75, 76-113 and 114 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods are drawn to different and distinct methods requiring different products to practice, different method steps, and result in materially different outcomes. The differences

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between the inventions are further underscored by their different search status and divergent classification.

Inventions 114 and 1-37 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the sequences can be identified by a variety of different methods known in the art.

Inventions 1-37 and 38-75, 76-113 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide sequences can be used to generate transgenic animals. Further, each of the methods may require different form or variant of the DNA set forth in claim 1. Additionally, the methods are different and unique from each other because they would require different types of starting material and different method steps to practice.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach